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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/405,050	09/27/1999	YEHUDA SHOENFELD	ZAP-ICIPCONC	9070

7590 04/29/2005

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT PAPER NUMBER

1645

DATE MAILED: 04/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/405,050

Applicant(s)

SHOENFELD ET AL.

Examiner

Mark Navarro

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 22-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 22-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 9, 2004 and December 8, 2004 have been entered.

Accordingly claims 1-11 and 22-29 remain pending in the instant application.

Claim Rejections - 35 USC § 112

1. The rejection of claims 1-11 and 22-29 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, a new matter rejection is maintained.

Applicants are asserting that Applicants provide support for treating metastasis, and lymphoma is specifically relevant in this context as a cancer. (Page 7, lines 11-13 and 15-20). Applicants further assert that Examples 1-5 demonstrate a direct effect of IVIG in inhibiting metastasis of two different cancers, a carcinoma and a sarcoma, establishing therefore, support for treating cancer metastasis, as a general principle, with IVIG. Applicants further assert that as set forth in MPEP 2164.02, that sufficient

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support for a claimed genus (treatment of cancer metastasis with IVIG) exists, since the Specification contains representative examples together with a statement applicable to the genus as a whole (Page 1, lines 2-4 and page 3, lines 15-17 and 19). Applicants further point toward Example 8, which demonstrates that lymphoma cells are responsive to IVIG, inhibiting cell proliferation, providing further support for the applicability of the instant invention, that of preventing metastasis, to lymphoma.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that the specification provides support for treating metastasis, and lymphoma is specifically relevant in this context as a cancer. (Page 7, lines 11-13 and 15-20). However, the specification sets forth that frequently, "metastasis of tumor cells will occur as a result of the physical manipulation of the tumor during surgery." The claims recite that the inhibition must take place in a mammal which has "metastatic lymphoma." However, there is no guidance within this passage of the specification to specifically isolate a subgenus of individuals who have active metastasis from those who do not for treatment, let alone any mention pertaining specifically to lymphomas, as recited in the instantly filed claims.

Second, Applicants assert that Examples 1-5 demonstrate a direct effect of IVIG in inhibiting metastasis of two different cancers, a carcinoma and a sarcoma, establishing therefore, support for treating cancer metastasis, as a general principle, with IVIG. However, Applicants are directed to their own arguments. They correctly recite that "One skilled in the art will readily recognize that cancerous cells that

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metastasize are phenotypically distinct from cells that remain at the primary tumor site.”

This phenotypical distinction is several fold more pronounced with different types of cancers, lymphomas, to which the claims are directed versus carcinomas and sarcomas as set forth in the Examples.

Third, Applicants assert that as set forth in MPEP 2164.02, that sufficient support for a claimed genus (treatment of cancer metastasis with IVIG) exists, since the specification contains representative examples together with a statement applicable to the genus as a whole (Page 1, lines 2-4 and page 3, lines 15-17 and 19). However, Applicants claims are not directed to a genus, rather the claims are directed to treating a subpopulation, (i.e., only those who have current metastatic lymphoma). It is this limitation, selection of only those who have metastatic lymphoma, which is deemed to be new matter.

Finally, Applicants point toward Example 8, which demonstrates that lymphoma cells are responsive to IVIG, inhibiting cell proliferation, providing further support for the applicability of the instant invention, that of preventing metastasis, to lymphoma. However, Applicants will note that Example 8 was carried out *in vitro*. No determination was made nor could have possibly been made as to whether the lymphoma had metastasized.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

Double Patenting

2. The rejection of claims 1-11 and 22-29 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 5,965,130 is maintained.

It is noted that Applicants have indicated a willingness to submit a terminal disclaimer upon an indication that all other rejections are withdrawn. However, until a terminal disclaimer is made of record, this rejection is maintained for reasons of record.

3. The rejection of claims 1-11 and 22-29 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,562,902 is maintained.

It is noted that Applicants have indicated a willingness to submit a terminal disclaimer upon an indication that all other rejections are withdrawn. However, until a terminal disclaimer is made of record, this rejection is maintained for reasons of record.

All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Navarro
Primary Examiner
April 28, 2005